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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,279	06.09/2000	Katayoon Dehesh	15597/01/US	3330

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ARNOLD & PORTER  
IP DOCKETING DEPARTMENT; RM 1126(b)  
555 12TH STREET, N.W.  
WASHINGTON, DC 20004-1206

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

25

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/591,279

Applicant(s)

DEHESH ET AL.

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4-7 and 29-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-7, 29-34, 39, 42, 44-46 and 51-64 is/are rejected.
- 7) ☒ Claim(s) 35-38, 40, 41, 43 and 47-50 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Status of the Application***

- [1]** Claims 4-7 and 29-64 are pending in the application.
- [2]** Applicant's cancellation of claims 1-3, amendment to claims 4-7 and 28-38, and addition of claims 39-64 in Paper No. 24, filed June 06, 2003, is acknowledged.
- [3]** Applicant's arguments filed in Paper No. 24 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [4]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### ***Sequence Compliance***

- [5]** It is noted that applicant has submitted a substitute sequence listing in computer readable form (CRF), a paper copy thereof, and a statement that the CRF and the paper copy of the sequence listing are identical filed in Paper No. 16. This substitute sequence listing has been entered into the database. However, the examiner can find no paper copy of the sequence listing or statement that the CRF and the paper copy of the sequence listing are identical. In order to be fully sequence compliant, the examiner requests that applicant submit a paper copy of the sequence listing as filed in Paper No. 16 and a statement that the CRF and the paper copy of the sequence listing are identical.

### ***Claim Objections***

- [6]** Claim(s) 7 is/are objected to for grammatical errors. The following suggestion(s) is/are provided to correct the error(s): a) insert "of" between "protein" and "claim" in line 2 of claim 7.

### ***Claim Rejections - 35 USC § 112, Second Paragraph***

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[7] Claims 39, 42, and 53-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[8] Claim 39 is confusing in that the claim indicates that alanine can be at position 108 and replaced with an alanine. However, claim 4, from which claim 39 depends indicates that the substitution is of a nonpolar side chain to a *different* side chain. It is suggested that applicant clarify the meaning of the claim.

[9] Claim 42 is confusing in the recitation of "the residue at position 133 of SEQ ID NO:47 is selected from the group consisting of phenylalanine and isoleucine, and leucine". According to MPEP § 2173.05(h), this is an improper alternative expression in a Markush group. It is suggested that applicant clarify the meaning of the claim.

[10] Claim 53 (claims 54-64 dependent therefrom) is unclear in the recitation of "elongator molecule". The examiner can find no definition for the meaning of the term in the specification and the meaning of the term is unclear. It is suggested that applicant clarify the meaning of the term.

***Claim Rejections - 35 USC § 112, First Paragraph***

[11] Claims 4-7, 29-34, 44-46, and 51-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claims 4 (claims 5-7, 29, 44-46 dependent therefrom), 30 (claims dependent 31-34, 51, and 52 therefrom), 53 (claims 54-58 dependent therefrom) are drawn to an engineered beta-KAS with a substitution of a residue selected from those recited amino acid positions wherein the substitution is of a nonpolar side chain to a different nonpolar side chain. Applicant states at page 10 of Paper No. 24, "[n]o new matter enters by way of the present amendment". However, the examiner has reviewed applicant's statement of support for the amended claims and the corresponding teachings in the

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specification (page 10, lines 7-10 of Paper No. 24) and can find no support in the claims, drawings or specification as originally filed for amino acid substitution of a nonpolar side chain to a different nonpolar side chain. It is suggested that applicant amend the claims so that the claims no longer recite new matter, or direct the examiner to support for the above identified claim limitation in the specification.

### **Conclusion**

**[12]** Status of the claims:

- Claims 4-7 and 29-64 are pending.
- Claims 4-7, 29-34, 39, 42, 44-46, and 51-64 are rejected.
- Claims 35-38, 40, 41, 43, and 47-50 are objected to as being dependent upon a rejected base claim.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman  
Patent Examiner  
Art Unit 1652

*Richard A. Smith*  
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*X*